No. 21-10994

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

JOHN D. CARSON, SR.,
Plaintiff-Appellant,
v.

MONSANTO COMPANY,
Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Georgia,
No. 4:17-cv-00237-RSB-CLR, Hon. R. Stan Baker

EN BANC BRIEF FOR PLAINTIFF-APPELLANT JOHN D. CARSON, SR.

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February 13, 2023

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CERTIFICATE OF INTERESTED PERSONS

Under Federal Rule of Civil Procedure 26.1 and Eleventh Circuit Rules 26.1-1, 26.1-2(d), and 28-1(b), undersigned counsel for Appellant John D. Carson, Sr. certifies that the following is a full and complete list of all persons, firms, associations, partnerships, and corporations, including subsidiaries, conglomerates, affiliates, parent corporations, and other legal entities having an interest in the outcome of this case:

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36. Postman, Warren, Attorney for *Amici Curiae* William W. Buzbee, Daniel Farber, Thomas O. McGarity, Paul McGreal, David Rubenstein, and Ernest A. Young in *Hardeman v. Monsanto Co.*, No. 19-16636 (9th Cir.)

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38. Ray, Hon. Christopher L., United States Magistrate Judge

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81. Steptoe & Johnson LLP

82. United Farm Workers

83. UFW Foundation

February 13, 2023 *_/s/ David C. Frederick_*
David C. Frederick

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STATEMENT REGARDING ORAL ARGUMENT

The Court has ordered that: "Oral argument will be conducted the week of June 12, 2023 in Atlanta, Georgia." Doc.115.

INTRODUCTION

Monsanto has known for decades that its popular weedkiller, Roundup, can cause cancer. But the company has refused to make the product safer or at least to warn consumers – particularly long-term users – that they should exercise caution and wear protective gear. Instead, Monsanto has hidden Roundup's defects and run television ads featuring people spraying Roundup in shorts and without gloves. Monsanto has pressed every court to consider failure-to-warn claims against the company to be preempted. Every appellate court to consider that argument has rejected it.

Appellant Dr. John D. Carson, Sr., is one of Monsanto's victims. Unaware of the dangers, he used Roundup for decades before being diagnosed with malignant fibrous histiocytoma, a soft-tissue cancer. Hundreds of thousands of ordinary citizens like Carson have suffered through illness – and even death – because Monsanto chose to pad its profits rather than warn them of the risks of Roundup.

In this Court, echoing arguments already rejected by multiple appellate courts, Monsanto argues that Carson's state-law failure-to-warn claims are preempted by the Federal Insecticide, Fungicide, and

Rodenticide Act, 7 U.S.C. §§ 136-136y, or FIFRA. The panel correctly dismissed that argument. In *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), the Supreme Court held that FIFRA preempts only state-law labeling requirements that are broader than FIFRA's own misbranding prohibition. Failure-to-warn claims parallel that prohibition, so they are not preempted.

To support its preemption argument, Monsanto relies on agency actions that have been either vacated or retracted, so they lack any force of law, let alone one that might preempt. Although EPA re-registered Roundup on an interim basis after an 11-year proceeding, concluding for purposes of registration that the active ingredient in Roundup was "not likely to be carcinogenic," the Ninth Circuit vacated that "not likely" conclusion as the hallmark of arbitrary action and not based on substantial evidence. A letter from a subordinate EPA official advising that cancer warnings should not be given was rooted in the same vacated EPA assessment and in any case later was retracted by a higher EPA official.

Even if those agency actions still reflected EPA's position, they would lack the force of law to preempt. As *Bates* and multiple courts of

appeals have held, the text of FIFRA itself provides that registration of a pesticide is not a defense to misbranding, or to parallel state failure-to-warn claims – a reading shared by the United States in a recent submission to the Supreme Court. Carson's state-law claims are not preempted.

JURISDICTIONAL STATEMENT

The district court had diversity jurisdiction under 28 U.S.C. § 1332 because the parties are citizens of different States and the amount in controversy exceeds $75,000. The district court dismissed all claims on March 22, 2021, App.106,[1] and Carson timely appealed on March 26, 2021, App.108-09. The Clerk entered final judgment on March 30, 2021. Supp.App.434. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Whether FIFRA preempts Carson's failure-to-warn claim.

[1] "App." refers to Carson's appendix at Doc.28, and a second volume filed here at Doc.123. "Supp.App." refers to Monsanto's three supplemental appendix volumes at Docs.51-1, 51-2, and 51-3.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

1. FIFRA regulates "the use, as well as the sale and labeling, of pesticides." *Bates*, 544 U.S. at 437. As relevant here, the statute proscribes marketing "any pesticide which is . . . misbranded." § 136j(a)(1)(E).[2] A pesticide is "misbranded" if its label contains a statement that is "false or misleading," § 136(q)(1)(A), or omits adequate instructions for use, necessary warnings, or cautionary statements, § 136(q)(1)(F), (G).

If EPA determines a pesticide is misbranded, it may cancel the pesticide's registration, § 136d(b), issue "stop sale, use, or removal" orders, § 136k(a), and seize misbranded products, § 136k(b). Manufacturers that sell misbranded products face civil and criminal penalties. § 136*l*.

2. FIFRA requires pesticide manufacturers to register their products with EPA. § 136a(a). The agency will register a pesticide if it determines – based on data the manufacturer submits – that (1) the product will not cause unreasonable harm to humans and the

[2] Except where noted, U.S. Code citations are to Title 7.

environment, and (2) the product label is not "misbranded" under FIFRA. § 136a(c)(5)(B)-(D). EPA re-reviews a pesticide's registration, including its effects on human health, every 15 years. § 136a(g)(1)(A).

FIFRA confirms that obtaining registration does not relieve the registrant of liability if the pesticide is misbranded. "In no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA]." § 136a(f)(2). Instead, registration is merely "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions." *Id.* "Because it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded, manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements." *Bates*, 544 U.S. at 438.

3. FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Id.* at 450. Indeed, States may ban a federally registered pesticide, even if EPA does not consider it misbranded. *Id.* at 446; *see* § 136v(a) ("A State may regulate the sale or use of any federally registered pesticide or device in the State . . . .").

The only statutory limit on state authority is a "narrow" preemption provision, *Bates*, 544 U.S. at 452, which "prohibits only

state-law labeling and packaging requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA," *id.* at 447 (quoting § 136v(b)).

B. Factual Background

Roundup is a weedkiller developed by Monsanto. It contains the active ingredient glyphosate, which kills plants at their roots. App.14 (¶ 13); *see also Hardeman v. Monsanto Co.*, 997 F.3d 941, 951 n.1 (9th Cir. 2021), *cert. denied*, 142 S. Ct. 2834 (2022); *Pilliod v. Monsanto Co.*, 282 Cal. Rptr. 3d 679, 689 (Cal. Ct. App. 2021), *cert. denied*, 142 S. Ct. 2870 (2022); *Chapman v. Monsanto Co.*, 2022 WL 3971287, at *8 (S.D. Tex.).[3] Roundup was the first glyphosate product registered by EPA.

[3] *Chapman* and *Hardeman* arose from federal multidistrict litigation, *In re Roundup Products Liability Litigation*, No. 3:16-md-02741 (N.D. Cal.), and *Pilliod* arose in state court. *Hardeman* and *Pilliod* affirmed jury verdicts against Monsanto on appeal; and *Chapman*, after remand from the MDL court, denied Monsanto's motion for summary judgment and set the case for trial. All three decisions reviewed the evidence of Monsanto's internal science and communications about Roundup – evidence Carson would get in discovery if the case went to trial.

Monsanto long has marketed Roundup as a "safe" general-purpose herbicide. App.14 (¶ 13).[4] The Roundup label "said nothing about wearing a mask or gloves when using it." *Pilliod*, 282 Cal. Rptr. 3d at 692. To the contrary, Monsanto's television commercials have depicted people "spraying Roundup in shorts and without gloves," *id.*, or have assured viewers that "Roundup can be used where kids and pets will play," App.20 (¶ 31). In 1996, after the New York Attorney General sued Monsanto, the company stopped publishing advertisements in that state that depicted its glyphosate-containing products as safe and harmless. App.21 (¶ 33).

1. Monsanto's mid-1970s registration of Roundup rested on falsified studies

Monsanto has had EPA's approval to sell glyphosate-based weedkillers since the mid-1970s. App.14 (¶ 13). To obtain that approval, Monsanto submitted studies testing whether glyphosate caused cancer or cell mutations in animals. App.16 (¶ 21). The company contracted Industrial Bio-Test Laboratories, or IBT), a commercial laboratory, to conduct the studies. App.17 (¶ 23).

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[4] Roundup is classified as a pesticide under FIFRA. *See* § 136(t), (u); *Bates*, 544 U.S. at 434 n.1.

IBT's studies were fraudulent, as both EPA and the Food and Drug Administration later found. App.17 (¶ 24). After finding "routine falsification of data" at IBT, one EPA reviewer stated it was "hard to believe the scientific integrity of the studies." *Id.*; *see Pilliod*, 282 Cal. Rptr. 3d at 710 ("fraudulent data" from IBT). Three top IBT executives were convicted of criminal fraud in 1983. App.17 (¶ 25).

IBT's fraud surfaced in 1976. App.17 (¶ 24). Yet Monsanto did not inform consumers about the fraud or remove Roundup from the market. App.18 (¶ 27); *see Pilliod*, 282 Cal. Rptr. 3d at 712. A 1983 EPA report explained that, after IBT's fraud was exposed, some experts advocated "that all 212 pesticides tested in whole or in part by IBT be removed from the market pending retesting." *Pilliod*, 282 Cal. Rptr. 3d at 711 n.20. But "that option [wa]s not available under [then-]current law." *Id.*

Nearly a decade passed before a valid study assessed the carcinogenicity of glyphosate. App.16 (¶ 21). In 1985, EPA reviewed studies showing that glyphosate could cause cancer in laboratory animals. *Id.* Based on that review, EPA classified glyphosate as a possible human carcinogen. *Id.*; *see Hardeman*, 997 F.3d at 951.

During its first two decades on the market, Roundup had "limited utility to farmers because it killed all vegetation in an application area." *NRDC v. EPA*, 38 F.4th 34, 41 (9th Cir. 2022). In the mid-1990s, Monsanto developed "Roundup Ready" seeds genetically modified to tolerate glyphosate, and "glyphosate use skyrocketed." *Id.*; App.18 (¶ 29). In 2000, Monsanto made nearly $2.8 billion in sales of Roundup. App.18-19 (¶ 30).

2. Studies in the late 1990s showed glyphosate was genotoxic, but Monsanto refused further testing

In the late 1990s, "four separate studies concluded that glyphosate was possibly genotoxic." *Chapman*, 2022 WL 3971287, at *8; *see Hardeman*, 997 F.3d at 951; *Pilliod*, 282 Cal. Rptr. 3d at 691. Genotoxic substances damage genetic information in cells, causing mutations that may lead to cancer. *See Pilliod*, 282 Cal. Rptr. 3d at 689 n.2. Monsanto hired genotoxicity expert Dr. James Parry to review the studies. *Chapman*, 2022 WL 3971287, at *8. Dr. Parry concluded "glyphosate could be genotoxic" and "suggested a battery of tests that Monsanto could conduct" to learn more. *Id.*

Monsanto did not share Dr. Parry's report or suggestions with EPA. *Id.* at *9. Nor did it "conduct any of Dr. Parry's suggested tests."

Id.[5] After reading one of Dr. Parry's reports, Dr. William Heydens, Monsanto's Product Safety Assessment Strategy Lead, candidly wrote to colleagues:

> Let's step back and look at what we are really trying to achieve here. We want to find/develop someone who is comfortable with the genotox profile of glyphosate/Roundup and who can be influential with regulators and Scientific Outreach operations when genotox issues arise. My read is that Parry is not currently such a person, and it would take quite some time and $$$/studies to get him there. We simply aren't going to do the studies Parry suggests. Mark, do you think Parry can become a strong advocate without doing this work . . . ? . . . If not, we should ***seriously*** start looking for one or more other individuals to work with. Even if we think we can eventually bring Parry around closer to where we need him, we should be currently looking for a second/back-up genotox[] supporter. We have not made much progress and are currently very vulnerable in this area. We have time to fix that, but only if we make this a high priority now.

Pilliod, 282 Cal. Rptr. 3d at 723 (alterations omitted); *see also* *Chapman*, 2022 WL 3971287, at *9. Another Monsanto employee later

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[5] Monsanto's failure to share the Parry report with EPA itself was a violation of FIFRA, which requires manufacturers to report "factual information regarding unreasonable adverse effects on the environment of [a] pesticide" to EPA on an ongoing basis, § 136d(a)(2); *see* 40 C.F.R. § 159.158(a). In other cases, Monsanto failed to "point[] to record evidence showing that it was . . . not required to submit the 1999 Parry report to the EPA as part of its § 6(a)(2) [§ 136d(a)(2)] reporting duty for its glyphosate registration." *Chapman*, 2022 WL 3971287, at *13; *see Pilliod*, 282 Cal. Rptr. 3d at 723 n.33.

wrote to Dr. Heydens that if "somebody came to me and said they wanted to test Roundup I know how I would react – with serious concerns." *Chapman*, 2022 WL 3971287, at *9; *see also Hardeman*, 997 F.3d at 971.

Monsanto found another expert to work with. In 1999, in parallel with Dr. Parry's review, Monsanto retained Dr. Gary Williams, a pathologist at New York Medical College. *See Chapman*, 2022 WL 3971287, at *9. Dr. Williams published an article in 2000 concluding that "under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans." *Id.* But "neither Dr. Williams nor any other listed author wrote the article. Monsanto ghostwrote the article." *Id.*

Monsanto then used the article as "an invaluable asset" in "responses to agencies," "Scientific Affairs rebuttals," and "[r]egulator reviews." *Id.* (alteration by the court). At the same time, "Monsanto did not disclose to the EPA that it ghostwrote the article." *Id.* EPA later

"relied on the Williams study in its 2017 evaluation of glyphosate's 'carcinogenic potential.'" *Id.*[6]

In sum, "after its own hired expert, Dr. Parry, found that glyphosate – alone and when mixed with other chemicals in Roundup – had increased genotoxic risks, evidence was sufficient to infer that Monsanto largely failed to perform further studies. Instead, Monsanto helped author an article downplaying glyphosate's health and safety concerns." *Hardeman*, 997 F.3d at 971.

3. Monsanto's early 2000s internal communications show it resisted testing Roundup as formulated

a. Glyphosate is not the only ingredient in Roundup; the product also contains a surfactant. In the United States, the surfactant is polyethoxylated tallow amine, or POEA. *Pilliod*, 282 Cal. Rptr. 3d at 691. Surfactants decrease surface tension. POEA therefore enables Roundup to penetrate the waxy surface of a leaf, to kill the weed at its roots – or to penetrate human skin.

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[6] *See Chapman*, 2022 WL 3971287, at *9 (citing Office of Pesticide Programs, EPA, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 22, 98, 155 (Sept. 12, 2016), www.epa.gov/sites/default/files/201609/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf. *See* Supp.App.189, 266, 326 (similarly relying on the Williams article in a December 2017 revision of the same EPA paper).

POEA makes Roundup more genotoxic. An expert at one trial testified that POEA and other ingredients make Roundup "about 50 times more genotoxic than glyphosate alone." *Id.* at 695. As a result, POEA is banned in Europe, where Monsanto now sells Roundup with a less toxic surfactant. *Id.* at 691.

"In 2010, when discussion was beginning about banning POEA in Europe, Dr. William Heydens, Monsanto's 'product safety assessment strategy lead,' wrote in an email that Monsanto should defend the use of POEA even as it was being phased out because of concern that a ban on the substance would lead to a 'domino effect' in other parts of the world." *Id.* And "Dr. Heydens wrote in a 2015 email that Monsanto believed that 'the surfactant in the formulation . . . played a role' in a tumor promotion study." *Id.*

b. Monsanto never has tested whether Roundup as formulated – which contains glyphosate, POEA, and other ingredients – causes cancer. In 2002, Dr. Heydens emailed Donna Farmer, another Monsanto toxicologist, suggesting Monsanto "re-visit" the genotoxicity of Roundup; Dr. Heydens noted in that email that "[g]lyphosate is OK but the formulated product (and thus the surfactant) does the damage."

Chapman, 2022 WL 3971287, at *9. In a 2009 email, Dr. Farmer wrote that "Monsanto could not 'say that Roundup does not cause cancer [because Monsanto had] not done carcinogenicity studies with Roundup.'" *Id.* (alteration in original).

Nor has EPA made any formal findings about Roundup's carcinogenicity. In 2017, as part of its re-registration review of glyphosate that began in 2009, EPA determined it could not reach "a conclusion regarding the association between glyphosate exposure and risk of [non-Hodgkin lymphoma]."[7] EPA explained that the data were uncertain, partly because "farmers and other applicators apply *formulations, not the active ingredient alone*."[8] It admitted that EPA's advisors had "conflicting views on how to interpret the overall results for [non-Hodgkin lymphoma]."[9] And it acknowledged the need for more

[7] Office of Pesticide Programs, EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* 68 (Dec. 12, 2017), https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=534487 (Supp.App.235).

[8] *Id.* at 137 (emphasis added) (Supp.App.304).

[9] *Id.* at 67 (Supp.App.234).

research "to determine whether formulation components, such as surfactants, influence the toxicity of glyphosate formulations."[10]

In April 2019, EPA noted that "[m]any commenters expressed concerns that glyphosate formulations are more toxic than glyphosate alone and questioned the toxicity of inert ingredients and the lack of transparency for inert ingredients and other contaminants in pesticide products."[11] In response, EPA acknowledged that "few research projects" had tried to compare "technical grade glyphosate" to glyphosate-based formulations like Roundup.[12] EPA said "[i]f at any time, information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, the EPA intends to review it and determine the appropriate regulatory action."[13] *See Hardeman*, 997 F.3d at 952 (same).

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[10] *Id.* at 144 (Supp.App.311).

[11] EPA, *Glyphosate: Proposed Interim Registration Review Decision* 10, No. 0178 (Apr. 2019), http://tinyurl.com/y6h2u8w6.

[12] *Id.* at 11.

[13] *Id.*

4. IARC classified glyphosate as a probable carcinogen in 2015

"In 2015, a working group at the International Agency for Research on Cancer ('IARC'), an agency of the World Health Organization," concluded that glyphosate "is 'probably carcinogenic to humans.'" *Id.* at 951 (quoting IARC report); *NRDC*, 38 F.4th at 41 (same); *see* App.21-25. Soon after, other countries issued certain bans of Roundup. *See* App.26-27.

In 2017, based on the 2015 IARC finding, California categorized glyphosate as a chemical known to the State to cause cancer and required a warning label on glyphosate products. *See Hardeman*, 997 F.3d at 951-52; Cal. Office of Env't Health Hazard Assessment, *Glyphosate*, https://oehha.ca.gov/proposition-65/chemicals/glyphosate (last visited Feb. 13, 2023).

5. An EPA official eventually concluded glyphosate manufacturers may include cancer warnings

In August 2019, the Director of the Registration Division within EPA's Office of Pesticide Programs issued a letter to all glyphosate-based product registrants in reaction to that California warning requirement. Supp.App.11-12 ("August 2019 Letter"). The letter stated

EPA would no longer approve labeling that warned consumers glyphosate was a chemical known to California to cause cancer, and that manufacturers must remove such a glyphosate-based cancer warning. *Id.* The letter, just over a page, explained only that its conclusion tracked certain international sources and EPA's 2017 re-registration review. *See id.*

In April 2022, a higher-ranking EPA official, the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, wrote a letter to California regulators retracting the prohibition asserted in the August 2019 Letter. *See* App.119-20 (Doc.83, Rule 28(j) submission) ("April 2022 Letter").[14] That letter reported "EPA could approve" California's newly proposed glyphosate-specific warning, which referenced both the IARC's conclusion glyphosate is carcinogenic and EPA's conclusion to date that it is not, explaining such a warning "would not be considered misbranded." *Id.*

[14] *See* EPA, *Organizational Chart* (Sept. 24, 2022), www.epa.gov/aboutepa/epa-organization-chart; EPA, *Organization Chart for the Office of Chemical Safety and Pollution Prevention (OCSPP)* (Nov. 1, 2022), www.epa.gov/aboutepa/organization-chart-office-chemical-safety-and-pollution-prevention-ocspp.

6. The United States has maintained before the Supreme Court that EPA registration decisions do not preempt state-law claims

In May 2021, the Ninth Circuit in *Hardeman* affirmed a jury verdict that Roundup caused Edwin Hardeman's cancer. The court rejected Monsanto's preemption claim because "the EPA actions that Monsanto alleges preempt Hardeman's claims" – registration of Roundup and the August 2019 Letter – "do not carry the force of law." *Hardeman*, 997 F.3d at 956.

Monsanto sought certiorari. The Supreme Court called for the views of the Solicitor General. The United States opposed certiorari, arguing *Hardeman* was correctly decided. App.122-51 ("SG *Hardeman* Br.").[15] The United States said "EPA's approval of pesticide labeling without a chronic-risk warning is not naturally characterized as a FIFRA 'requirement' that no such warning appear," noting that a "requirement is a rule of law that must be obeyed." App.138-39 (quoting *Bates*, 544 U.S. at 445). The Supreme Court denied certiorari.

[15] Brief for the United States as Amicus Curiae, *Monsanto Co. v. Hardeman*, No. 21-241 (U.S. May 10, 2022), 2022 WL 1489462.

Monsanto Co. v. Hardeman, 142 S. Ct. 2834 (2022); *see also Monsanto Co. v. Pilliod*, 142 S. Ct. 2870 (2022) (likewise denying certiorari).

7. The Ninth Circuit vacated EPA's re-registration conclusion that glyphosate is not likely to cause cancer

a. FIFRA requires that "registrations of pesticides are to be periodically reviewed" by EPA every 15 years. § 136a(g)(1)(A). In 2009, EPA started its re-registration review of glyphosate. EPA "decided to conduct registration review on glyphosate, an active ingredient," rather than to "evaluate each pesticide registration [such as Roundup] individually." *NRDC*, 38 F.4th at 41 n.2.[16]

EPA's re-registration proceeding lasted 11 years. The proceeding resulted in an interim, rather than a final, registration decision, which EPA issued in January 2020. *See* Supp.App.386-421.[17] The agency, in its 2020 Interim Decision, "determined that there are no risks to human

[16] EPA may evaluate a "pesticide case . . . composed of 1 or more active ingredients and the products associated with the active ingredients," or it may evaluate each pesticide product registration individually. § 136a(g)(1)(A)(iii).

[17] EPA regulations "permit, but do not require, EPA to issue an 'interim registration review decision' prior to the registration review decision." *NRDC*, 38 F.4th at 40 (quoting 40 C.F.R. § 155.56).

health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." Supp.App.395; *NRDC*, 38 F.4th at 43.

b. Following a challenge, the Ninth Circuit vacated the agency's "not likely to be carcinogenic" conclusion, finding EPA's reasoning was "the hallmark of arbitrary action." *NRDC*, 38 F.4th at 51 (internal quotation marks omitted). The agency's "not likely" determination was "in tension with parts of the agency's own analysis and with the guidelines it purports to follow," and thus not supported by "substantial evidence." *Id.* at 46, 51.

First, the court found EPA's "choice of the 'not likely' descriptor" for glyphosate "conflict[ed] with" its analysis of epidemiological studies. *Id.* at 46. EPA uses the "not likely" descriptor when there are "robust" data showing "there is no basis for human hazard concern." *Id.* But here EPA had ample reason for concern: "most studies EPA examined indicated that human exposure to glyphosate is associated with an at least somewhat increased risk of developing [non-Hodgkin lymphoma]." *Id.* And in an earlier "Cancer Paper" the agency had concluded "the association between glyphosate exposure and risk of [cancer] cannot be

determined based on the available evidence." *Id.* The court held EPA could not "reasonably treat its inability to reach a conclusion about [cancer] risk as consistent with a conclusion that glyphosate is 'not likely' to cause cancer." *Id.* at 47.

Second, EPA's "not likely" conclusion did not "withstand[] scrutiny under the agency's own framework." *Id.* For example, EPA guidelines describe how the agency should use historical-control data that show how often certain tumors occur naturally in animals. That data can either "bolster" or "undermine" study results: if a study uncovers rare tumors, then "the result is in fact unlikely to be due to chance," while a study that turns up only common tumors is of "reduce[d] . . . importance." *Id.* at 47-48. But for glyphosate "EPA use[d] this type of data *only* to discount studies indicating that glyphosate may cause tumors." *Id.* at 48 (emphasis added). This one-way ratchet drew criticism from an EPA scientific panel because it would "potentially introduce biases." *Id.* Rather than address those concerns, "the agency did not change the way in which it factored those data into its analysis." *Id.* This and other issues, *see*, *e.g.*, *id.* at 49 ("disregard of tumor results

occurring at high dosages"), rendered the "analysis underpinning EPA's 'not likely' descriptor . . . flawed." *Id.* at 47.

C. Procedural History

1. Appellant Dr. John D. Carson, Sr., a Georgia resident, routinely applied Roundup to his lawn for approximately thirty years. App.27 (¶ 60). In 2016, he was diagnosed with malignant fibrous histiocytoma. App.27 (¶ 61). He believes his long-term exposure to Roundup caused his cancer. App.27 (¶ 62).

Carson sued Monsanto in December 2017. App.12-43 (Complaint). He alleged strict liability for failure to warn under Georgia law, among other claims not relevant here. App.31-36 (Count II). Monsanto moved for judgment on the pleadings, and the district court held that FIFRA expressly preempted Carson's failure-to-warn claim because EPA had classified glyphosate as not likely to be carcinogenic to humans. App.95-96; *see* App.89-104 (Order).

The district court reasoned that "a warning on Roundup® that glyphosate causes cancer would be in direct conflict with the EPA's approved label because the EPA classifies glyphosate as 'not likely to be carcinogenic to humans' and considers glyphosate products with cancer

warnings to be 'misbranded,'" citing the August 2019 Letter targeting the California warning. App.95-96. The court did not have the benefit of the April 2022 Letter, which walked back the August 2019 Letter; the United States' May 2022 brief in *Hardeman*, which rejected Monsanto's preemption arguments; or the Ninth Circuit's June 2022 decision in *NRDC v. EPA*, which vacated EPA's "not likely" conclusion.

2. The parties reached a "high-low settlement" under which Dr. Carson will receive a greater settlement payment if he prevails on appeal. App.116. Dr. Carson timely appealed. *See* Supp.App.434; App.108-09. A panel of this Court reversed the district court's preemption holding, Docs.91-93, and Monsanto petitioned for rehearing *en banc,* Doc.94. In response, the panel vacated its July 12 opinion and replaced it with a revised opinion. Doc.104 ("Op.").

3. The revised panel opinion maintained its original conclusion that Carson's failure-to-warn claim is not preempted. Starting from FIFRA's text, the panel articulated three statutory rules.

First, a pesticide "can . . . be misbranded if the label does not 'contain directions for use' or 'a warning or caution statement' that is

'adequate to protect health and the environment.'" Op.5 (quoting § 136(q)(1)(F), (G)).

Second, "even with EPA oversight at the initial registration process, pesticide manufacturers have a perpetual duty to adhere to FIFRA's labeling requirements and to report any new adverse effects to the EPA." Op.5-6 (footnote omitted) (citing §§ 136j(a)(1)(E); 136a(f)(1); 136d(a)(2); 40 C.F.R. § 159.184)).

Third, FIFRA accounts for the possibility "EPA might just miss a misbranded label in the registration process . . . by explaining that '[i]n no event shall registration of an article be construed as a defense for the commission of any offense under [FIFRA].'" Op.6 (quoting § 136a(f)(2)) (alteration in original).

Examining Carson's claim against FIFRA, the panel said "the Georgia failure to warn claim simply enforces the FIFRA cause of action, so it is not expressly preempted." Op.9 (citing *Bates*, 544 U.S. at 447-48).

The panel next concluded EPA's "registration process" lacked the "force of law" because "it doesn't amount to a sufficiently formal proceeding . . . since it at most creates a rebuttable presumption of

compliance with FIFRA's registration process and nothing more." Op.10-11. It did not discuss the Ninth Circuit's June 2022 vacatur of EPA's "not likely to be carcinogenic to humans" conclusion.

Finally, the panel turned to "various EPA documents" cited by Monsanto, including the August 2019 Letter, concluding those documents likewise lacked the requisite "indicia of formality" to be preemptive. Op.11-13. It did not discuss the April 2022 Letter that retracted the August 2019 Letter.

The panel also rejected Monsanto's impossibility preemption claim for similar reasons. Op.11 n.11 ("Because . . . we have already determined that the EPA has not acted with the force of law and that FIFRA statutes are consistent with Georgia law, we do not address this argument further.") (citing *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678-79 (2019)).

4. Monsanto again sought rehearing *en banc*, which this Court granted, vacating the revised panel opinion. Doc.113-2. The Court ordered the parties to focus on two issues about when agency action has the "force of law" in the context of the term "requirements" as used in FIFRA's express preemption provision, § 136v(b). Doc.115.

SUMMARY OF ARGUMENT

This case presents the same issue that multiple appeals courts already have decided: Does FIFRA preempt state failure-to-warn claims involving Roundup? The answer is "no," as all those courts held. Neither express nor implied preemption apply.

I. FIFRA provides a decentralized regulatory scheme for pesticides that leaves a broad role for States. States can, for example, ban pesticides that EPA has approved. The only limitation on state authority is a preemption provision that prohibits state labeling requirements "in addition to or different from" the "requirements under [FIFRA]." § 136v(b). In *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), the Supreme Court held that "narrow" preemption provision did not cover state-law failure-to-warn claims that align with FIFRA's misbranding requirements. Carson's Georgia-law claim parallels those requirements by requiring health and safety warnings in narrower circumstances than FIFRA already does. So as the panel correctly concluded, Carson's claim is not preempted.

This Court asked how to identify a labeling "requirement" under FIFRA. The statutory text – particularly the misbranding provisions –

detail the labeling requirements. EPA can add to those requirements by refining FIFRA's misbranding provisions through notice-and-comment rulemaking. It has not done so.

Next, the Court asked if it must determine as a threshold question for preemption whether the agency action had force of law. The answer is "yes." Only agency actions with force of law have preemptive power, and only agency actions taken under congressionally delegated authority have force of law. For the same reasons, § 136v(b) cannot give preemptive effect to agency actions that lack force of law. *Bates* held that a federal "requirement" is a rule of law that must be obeyed, and only agency actions with force of law meet that description.

Monsanto's express-preemption arguments lack merit for several reasons. The company focuses on EPA's conclusion that glyphosate is "not likely to be carcinogenic" during its interim registration process. *First*, the Ninth Circuit vacated the "not likely" decision, which therefore has no legal effect. *Second*, FIFRA makes clear pesticide registration is not preemptive. Under the statute, registration is not a defense to misbranding, and a registered label can still be misbranded. So state-law claims that, like Carson's, functionally enforce the

statutory misbranding provisions are not misbranded. *Third*, EPA never has assessed the health risks of a glyphosate-based formulation like Roundup. EPA's registration of glyphosate therefore is not a labeling "requirement" that preempts Roundup claims.

II. Nor is there any basis for implied (impossibility) preemption. Because FIFRA has an express-preemption provision, there is no room for implied preemption, as Justice Thomas recognized in *Bates*. And even if implied preemption could apply, it does not here. To support implied preemption, Monsanto had to present clear evidence that EPA would reject whatever warning Carson's claim requires. No such evidence exists. Instead, a higher-ranking EPA official has said the agency would accept cancer warnings on products containing glyphosate. And EPA's interim conclusion that glyphosate is not likely to cause cancer has been vacated by the Ninth Circuit and remanded for notice and comment. There is no preemption.

STANDARD OF REVIEW

"Judgment on the pleadings is proper when . . . the movant is entitled to judgment as a matter of law." *Ortega v. Christian*, 85 F.3d 1521, 1524 (11th Cir. 1996). Whether a plaintiff's "state law claims are

preempted by . . . federal law is reviewed by this Court *de novo*." *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 767 (11th Cir. 1998). Likewise, the Court reviews *de novo* a district court grant of judgment on the pleadings, "accepting the facts in the complaint as true and viewing them in the light most favorable to the nonmoving party." *Horsley v. Feldt*, 304 F.3d 1125, 1131 (11th Cir. 2002).

ARGUMENT

I. Carson's Failure-To-Warn Claim Is Not Expressly Preempted

A. FIFRA Does Not Expressly Preempt State-Law Claims That Parallel The Statute's Misbranding Provisions

1. FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 450 (2005). Indeed, States may ban a federally registered pesticide, even if EPA does not consider it misbranded. *Id.* at 446 (citing § 136v(a)).

The only statutory limit on state authority is a "narrow" preemption provision, *id.* at 452, which "prohibits only state-law labeling and packaging requirements that are '*in addition to or different from*' the labeling and packaging requirements under FIFRA," *id.* at

447 (quoting § 136v(b)). FIFRA's express preemption or "Uniformity" provision thus provides:

> (a) In general
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

§ 136v(a)-(b).

2. "The proper inquiry" when determining whether FIFRA preempts a common-law claim "calls for an examination of the elements of the common-law duty at issue." *Bates*, 544 U.S. at 445. Even when a state-law claim addresses pesticide labeling, it is preempted only if it imposes requirements "in addition to or different from those required under [FIFRA]." § 136v(b). In *Bates*, the Supreme Court held that common-law duties are not preempted if they are "equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447; *see id.* at 454 ("[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer

is also liable for misbranding as defined by FIFRA."). In other words, FIFRA does not preempt state-law claims that impose "parallel requirements" to those in FIFRA. *Id.* at 447.

A state-law failure-to-warn claim merely provides a remedy for a manufacturer's failure to fulfill its duty to label its product for safe use. Although FIFRA itself "does not provide a federal remedy to [those] who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, nothing in § 136v(b) precludes States from providing such a remedy." *Id.* at 448. There is, of course, a "long history of tort litigation against manufacturers of poisonous substances." *Id.* at 450-51. Given this history, the Supreme Court has observed that "[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA." *Id.* at 451.

B. Carson's Failure-To-Warn Claim Parallels FIFRA's Misbranding Provisions So It Is Not Preempted

Carson's failure-to-warn claim under Georgia law imposes the same or narrower requirements as FIFRA's misbranding provisions. So as the panel correctly concluded, Carson's claim is not preempted.

First, Carson would have to prove at trial that Monsanto "fail[ed] to exercise reasonable care to inform [him] of [Roundup's] dangerous

condition[,] or of the facts which make it likely to be dangerous." Op.8-9 (quoting *Greenway v. Peabody Int'l Corp.*, 294 S.E.2d 541, 545-46 (Ga. Ct. App. 1982) (quoting, in turn, Restatement (Second) of Torts § 388 (Am. L. Inst. 1965, Oct. 2022 Update)). That common-law duty tracks § 136(q)(1)(G), which requires a warning "necessary" and "adequate to protect health."

Second, Carson's claim would require warnings in narrower circumstances than FIFRA does. FIFRA requires adequate safety warnings no matter whether the manufacturer knows of the risks and "regardless of the knowledge of the consumer." Op.9; *see* § 136(q)(1)(G). Georgia law, by contrast, requires a warning only if Monsanto "knows or has reason to know that [Roundup] is or is likely to be dangerous for the use for which it [wa]s supplied." Op.8-9. And Georgia law requires a warning only if consumers "who will be using the product do not realize the dangerous condition of the product." Op.9. The panel therefore correctly concluded that "the Georgia law failure to warn claim, if anything, imposes less of a duty on Monsanto than the FIFRA statute." *Id.*; *see Hardeman v. Monsanto Co.*, 997 F.3d 941, 955 (9th

Cir. 2021) (finding no preemption because FIFRA "is broader than California's requirement under negligence").[18]

Because Carson's failure-to-warn claim parallels FIFRA's misbranding provisions, it effectively enforces the statutory misbranding prohibition. "[A] state cause of action that seeks to enforce" those misbranding provisions "does not impose a requirement that is 'different from, or in addition to,' requirements under federal law," and so is not preempted. *Bates*, 544 U.S. at 447-48 (quoting *Lohr*, 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part)). The panel was correct.

C. Only Agency Actions Taken Under Delegated Authority Can Preempt Under FIFRA

This Court asked how "a reviewing court" should "identify the federal 'requirements . . . under this subchapter' to which § 136v(b) refers." Doc.115. The search for a FIFRA requirement begins with the

[18] FIFRA does not preempt narrower state-law requirements. "While such a narrower requirement might be 'different from' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule." *Bates*, 544 U.S. at 447 n.23 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (interpreting 21 U.S.C. § 360k(a)(1), which uses language similar to § 136v(b))).

statute's text – specifically, the statute's misbranding provisions. *Bates*, 544 U.S. at 447. Those provisions require, for example, that a pesticide label not contain "false or misleading" statements. § 136(q)(1)(A). If a state-law cause of action "adds some supplemental requirement of truthfulness" to that requirement, it "imposes a labeling requirement 'in addition to or different from' FIFRA's" and is therefore preempted. *Bates*, 544 U.S. at 456 (Thomas, J., concurring in the judgment in part and dissenting in part).

Only agency actions taken under delegated authority can supplement FIFRA's statutory requirements. In *Bates*, the Supreme Court described how EPA could preempt state-law failure to warn claims: through notice-and-comment rulemaking. The Court there wrote that, if EPA promulgates "regulations that refine or elaborate upon FIFRA's broadly phrased misbranding standards . . . in the future, they will necessarily affect the scope of pre-emption under § 136v(b)." 544 U.S. at 453 n.28. The agency has not done so here. As the United States has advised the Supreme Court: "Neither FIFRA nor its implementing regulations . . . specifically address warnings for chronic health risks like carcinogenicity." SG *Hardeman* Br. 10.

This Court next asked whether "a reviewing court" must "determine, as a threshold matter, whether federal agency action has the 'force of law.'" Doc.115. The answer is "yes." As the Supreme Court held in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), preemption can occur "only when and if the agency is acting within the scope of its congressionally delegated authority, for an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it." *Id.* at 1679 (cleaned up).

A reviewing court must therefore look first to FIFRA's text to see whether EPA action purporting to impose a preemptive requirement was done under authority delegated by Congress. "Agencies have only those powers given to them by Congress, and enabling legislation is generally not an open book to which the agency may add pages and change the plot line." *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) (cleaned up). "The Supremacy Clause thus requires that pre-emptive effect be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text." *Wyeth v.*

Levine, 555 U.S. 555, 586 (2009) (Thomas, J., concurring in the judgment).

Last, this Court asked whether an "express-preemption provision like § 136v(b)" can "give preemptive effect to a federal agency action that otherwise lacks the 'force of law.'" Doc.115. The answer is "no." A prerequisite to application of the Supremacy Clause is that the allegedly preemptive federal action be "Law." U.S. Const. art. VI, cl. 2. Yet FIFRA leaves plenty of scope for state law to operate. Section 136v(a) provides that "[a] State may regulate the sale or use of any federally registered pesticide or device in the State," and § 136v(b) only preempts state-labeling requirements "in addition to or different from those required under [FIFRA]." § 136v(a)-(b). So for there to be preemption, there first must be a "requirement" under FIFRA. As *Bates* made clear in interpreting § 136v(b): "A requirement is a rule of law that must be obeyed." 544 U.S. at 445. If an agency action "otherwise lacks the 'force of law'" as the question posits, then it is not "a rule of law that must be obeyed." An agency action that lacks the force of law therefore cannot preempt under § 136v(b).

D. Monsanto Identifies No Preemptive Action By EPA

In its petition, and before the panel, Monsanto raised the same express-preemption arguments that it has raised in *Hardeman*, *Pilliod*, and myriad other cases. Not one appellate judge – let alone panel – has accepted those arguments. Repetition has not made the arguments any less "incorrect." SG *Hardeman* Br. 6-7.

1. EPA's conclusion that glyphosate is "not likely to be carcinogenic" lacks any arguable force of law

Monsanto's cornerstone argument is that EPA's decision to register a pesticide and approve its label imposes a preemptive "requirement" under FIFRA. *See* Doc.107 at 8-18 ("Pet."). That argument always lacked merit, *see infra* pp.42-51, but it is even less persuasive now that the Ninth Circuit has vacated the reasoning EPA used when registering glyphosate.

a. After an 11-year re-registration process that began in 2009, EPA failed to sustain its conclusion that glyphosate was not likely to cause cancer. The Ninth Circuit held EPA lacked substantial evidence for that conclusion and that its reasoning to get there in its 2020 Interim Decision was "the hallmark of arbitrary action." *NRDC v. EPA*, 38 F.4th 34, 51 (9th Cir. 2022) (internal quotation marks omitted).

EPA's determination was "in tension with parts of the agency's own analysis and with the [EPA Cancer] guidelines it purports to follow." *Id.* at 46. In sum, the court held EPA could not "reasonably treat its *inability* to reach a conclusion about [cancer] risk as consistent with a conclusion that glyphosate is '*not* likely' to cause cancer." *Id.* at 47 (emphases added); *see supra* pp.20-21.

Because of EPA's inconsistent and faulty reasoning, its conclusion that glyphosate is "not likely" carcinogenic flunked substantial-evidence review. The Ninth Circuit thus "vacate[d]" "and remand[ed] for further analysis and explanation . . . including a new public-comment process." *NRDC*, 38 F.4th at 52 & n.14. The court "decline[d] to rule on any effect this vacatur might have on glyphosate's registration," including the possibility on remand of "deregistration" of formulated glyphosate products. *Id.* at 52 & n.13.[19]

b. Though glyphosate remains registered, whatever preemptive effect registration might have had has been nullified. Put differently, EPA's interim registration decision lacks force of law and cannot

[19] EPA did not seek rehearing or review by the Supreme Court, and the court's mandate issued. *See NRDC v. EPA*, No. 20-70787, Dkt. 143 (9th Cir. Aug. 24, 2022).

preempt Carson's claims. An agency decision that has been vacated has no legal effect. "In essence, a vacatur order takes the unlawful agency action off the books, which is an entirely appropriate response when a plaintiff successfully establishes that the agency's conduct violates the law." *Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 50 (D.D.C. 2020) (Jackson, J.) (cleaned up).[20]

In its petition, Monsanto relegates the Ninth Circuit's vacatur of EPA's "not likely" conclusion to a cryptic footnote, claiming the court "explain[ed] that its decision 'maintained the status quo.'" Pet. 6 n.2 (quoting *NRDC*, 38 F.4th at 52). That mischaracterization leaves the false impression that EPA's "not likely" conclusion was left unaffected by the court's vacatur.[21] In fact, the court of appeals "vacate[d] the human-health portion of EPA's Interim Decision" – that is, the

[20] *See* 5 U.S.C. § 706 (Administrative Procedure Act: a "reviewing court" may "hold unlawful and set aside agency action, findings, and conclusions"); Black's Law Dictionary (11th ed. 2019) (vacatur means the "act of annulling or setting aside"); *NRDC*, 38 F.4th at 51 ("[v]acatur is the traditional remedy for erroneous administrative decisions").

[21] Carson could have corrected this misimpression in a response to Monsanto's petition, but this Court's rules provide that a "response to a petition for en banc consideration may not be filed unless requested by the court." 11th Cir. R. 35-6.

conclusion that glyphosate is not likely carcinogenic – "and remand[ed] for further analysis and explanation." *NRDC*, 38 F.4th at 52. When deciding whether to order vacatur, the court merely noted that "no disruptive consequences will result from vacating the human-health portion of the Interim Decision because that portion simply maintained the status quo – the Interim Decision imposed no new mitigation measures associated with human health." *Id.* And though the court declined to "order deregistration" because it would be a "highly disruptive remedy," it explained that for EPA to reach the same "not likely" conclusion on remand its "explanation would need to be so different that we cannot make a confident prediction" whether the attempt would be lawful. *Id.* at 52 & nn.13-14.

c. After the Ninth Circuit's vacatur, EPA withdrew the interim decision. *See* EPA, *EPA Withdraws Glyphosate Interim Decision* (Sept. 23, 2022).[22] Even so, Monsanto cites EPA's statement that its "underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic in humans,

[22] www.epa.gov/pesticides/epa-withdraws-glyphosate-interim-decision.

remains the same." *Id.*; Pet.6 n.2. That bare (and incorrect) statement has no legal effect, much less a preemptive one. As the *NRDC* court held, and "EPA did not dispute," "vacatur of the human-health portion will require the agency to conduct a new public-comment process." 38 F.4th at 52 n.14 (citing 40 C.F.R. §§ 155.56, 155.58(a)).

More generally, an agency may not rely on a vacated rationale in taking any later action. Vacated actions are a nullity, with no legal effect. *See Kiakombua*, 498 F. Supp. 3d at 50. The D.C. Circuit therefore has explained that "[a]n agency cannot remedy a deficiency in one regulation by promulgating a new rule, equally defective for the same . . . reasons." *Action on Smoking & Health v. Civil Aeronautics Bd.*, 713 F.2d 795, 798-99 (D.C. Cir. 1983) (per curiam). And that court has vacated an agency order because it "relied not only on [an already vacated order] but also on its defective reasoning." *WorldCom, Inc. v. FCC*, 246 F.3d 690, 696 (D.C. Cir. 2001); *see also Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1810 (2019) (explaining that an agency in promulgating a new rule "couldn't rely on the [prior] rule, which had been vacated"); *Hawaii Longline Ass'n v. National Marine Fisheries Serv.*, 281 F. Supp. 2d 1, 26 (D.D.C. 2003) ("reliance on a vacated

[biological opinion] . . . is by definition arbitrary and capricious" and "provides [no] legal basis for the . . . Regulations").

If an agency may not rely on a vacated conclusion at all, then of course a vacated conclusion cannot preempt. *See supra* pp.33-36.

2. Congress did not delegate to EPA the authority to preempt through registration of a pesticide

a. Even if EPA's "not likely" conclusion had not been vacated, its decision to register a pesticide does not immunize the manufacturer from tort liability. Registration is not even the last word on whether the pesticide's labeling is misbranded. The agency determines whether a pesticide's warnings are "necessary" and "adequate to protect [public] health" based on material the manufacturer submits. § 136(q)(1)(G); *see* § 136a(c)(2), (c)(5)(B)-(D). If other information, like an "incident[] involving a pesticide's toxic effects" shows the labeling to be misbranded, *Bates*, 544 U.S. at 439, EPA's prior registration decision offers a manufacturer no safe harbor: "EPA may institute cancellation proceedings and take other enforcement action if it determines that a registered pesticide is misbranded." *Id.* (citation omitted).

A manufacturer cannot use EPA's registration of its pesticide "as a defense for the commission of any offense under [FIFRA]," including the

misbranding offense. § 136a(f)(2). Rather, registration is only "prima facie evidence" that the pesticide is not misbranded. *Id.*[23] As a result, even if EPA approved a label, "a judge or jury" could "find that [the] same label violates FIFRA." *Hardeman*, 997 F.3d at 956.

That is why *Bates* recognized a pesticide can be "registered but nevertheless misbranded." 544 U.S. at 438. "Against that backdrop," the United States has explained, "EPA's approval of pesticide labeling without a chronic-risk warning is not naturally characterized as a FIFRA 'requirement' that no such warning appear." SG *Hardeman* Br. 11-12.

If a pesticide is "registered but nevertheless misbranded," the manufacturer has a duty to update its label. *Id.* at 2. FIFRA does not authorize, much less require, a manufacturer to retain the label of a

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[23] Section 136a(f)(2) provides in full:

> (2) Registration not a defense
>
> In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

misbranded pesticide just because EPA registered the pesticide. Indeed, retaining a registered but misbranded label is not a "requirement" of FIFRA – it is a violation. And registration does not establish any relevant "requirement" that might supersede a duty under state law. For this reason – and because EPA's registration of glyphosate did not assess the health risks of glyphosate-based formulations like Roundup – EPA's registration of glyphosate does not preempt Carson's claims. *See Hardeman*, 997 F.3d at 956 ("[B]ecause EPA's labeling determinations are not dispositive of FIFRA compliance, they similarly are not conclusive as to which common law requirements are 'in addition to or different from' the requirements imposed by FIFRA."); *Indian Brand Farms, Inc. v. Novartis Crop Prot.*, 617 F.3d 207, 222 (2010) (similar).[24]

b. Monsanto contends § 136a(f)(2) "has 'no bearing on'" preemption because it "stands for the unremarkable proposition that a registration is not a defense against an allegation that a product

[24] *See also Blitz v. Monsanto Co.*, 317 F. Supp. 3d 1042, 1050 (W.D. Wis. 2018) (EPA registration and label approval are not requirements that can preempt failure-to-warn claims); *Carias v. Monsanto Co.*, 2016 WL 6803780, at *2 (E.D.N.Y.) (same); *Hernandez v. Monsanto Co.*, 2016 WL 6822311, at *7 (C.D. Cal.) (same).

violates the terms of that registration." Pet.11-12 (quoting *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994), and *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 45 (D.D.C. 2011)). But that narrow reading of the provision does not track its text, which establishes that registration is not a defense to "any offense" under FIFRA, not just violations of the terms of registration. § 136a(f)(2).

As the panel properly concluded, "Congress itself undermined the formality of EPA registration when it explained that EPA registration served only as prima facie evidence of compliance with the registration requirements of FIFRA." Op.10 (citing § 136a(f)(2)). "It would defy logic to say a rebuttable presumption carries the force of law necessary to have preemptive effect, as doing so would deny any ability to rebut the presumption." *Hardeman*, 997 F.3d at 957.

Monsanto claims *MacDonald*, in which a pre-*Bates* panel of the Fifth Circuit adopted its view of § 136a(f)(2), splits with *Hardeman*. Pet.11. But *MacDonald*, decided 11 years before *Bates*, is no longer good law. It was abrogated by *Bates*, as the Third Circuit recognized in *Indian Brand Farms*, 617 F.3d at 221-22 ("*Bates* introduced a different analysis of FIFRA preemption, one that compels us to depart from this

pre-*Bates* precedent."). Monsanto cannot manufacture a circuit split with an abrogated decision.

c. Section 136a(f)(2) also shows why Monsanto cannot rely on *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). *See* Pet.9-12. In *Riegel*, the Court held that FDA's premarket medical-device approval imposes "requirements" under the preemption clause of a Medical Device statute and preempts state failure-to-warn claims based on inconsistent duties. *See* 552 U.S. at 322-23, 327-30. The Court said FDA's premarket approval of the riskiest medical devices serves as conclusive evidence that "the approved form [of the devices] provides a reasonable assurance of safety and effectiveness." *Id.* at 323.

In contrast, FIFRA provides that registration is only "prima facie evidence" of compliance, § 136a(f)(2), not proof the labeling is "adequate to protect health," § 136(q)(1)(F), (G). And because a manufacturer with a registered product still could be liable for misbranding, it could be liable for state-law claims (like Carson's failure-to-warn claim) "that are fully consistent with federal requirements." *Bates*, 544 U.S. at 452.

More generally, the statutory schemes in *Riegel* and here are meaningfully different. The Medical Device Amendments "swept back

some state obligations and imposed a regime of detailed federal oversight," *Riegel*, 552 U.S. at 316, while FIFRA "authorizes a relatively decentralized scheme" that leaves States with broad power to regulate pesticide products – including the power to ban the sale of unsafe, but registered, pesticides, *Bates*, 544 U.S. at 450 (citing § 136v(a)). Thus, "different federal statutes and regulations may . . . lead to different pre-emption results." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 626 (2011).

For medical devices, "premarket approval is specific to individual devices," requiring FDA to determine the device "offers a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 322-23. By contrast, FIFRA's misbranding provisions impose only "general standards." *Bates*, 544 U.S. at 453 n.27; *see Lohr*, 518 U.S. at 501 (no preemption when federal requirements "reflect[ed] important but entirely generic concerns about device regulation generally"). And EPA has acknowledged that it has not specifically evaluated glyphosate "formulations" like Roundup. *See supra* pp.13-15; *Hardeman*, 997 F.3d at 952 ("EPA explained that 'there are few research projects that have attempted to directly compare technical grade glyphosate to the formulations under the same experimental design,' but '[i]f at any time,

information becomes available that indicates adverse human health effects of concern for exposure to glyphosate or its formulations, EPA intends to review it and determine the appropriate regulatory action.'") (citation omitted).

d. Monsanto's reliance on *Merck*, which did not even implicate express preemption, likewise fails. *See* Pet.12-14. That case followed *Wyeth v. Levine*, in which the Court rejected implied (or impossibility) preemption from FDA's approval of a drug label. *See Merck*, 139 S. Ct. at 1676-78 (discussing *Wyeth*). The Court explained that – similar to FIFRA here – "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times," and "when the risks of a particular drug become apparent, the manufacturer has 'a duty to provide a warning that adequately describes that risk.'" *Id.* at 1677 (quoting *Wyeth*, 555 U.S. at 570-71) (alteration omitted). FDA regulations allowed drug manufacturers to change a label without prior FDA approval, and for implied or impossibility preemption the Court required "clear evidence" FDA would have rejected such a change. *Id.* at 1678 (emphasis omitted) (quoting *Wyeth*, 555 U.S. at 571).

Here, Monsanto invokes an FDA regulation that allows that agency to reject a label change, contending such "process is not specifically provided for by statute, leaves no trace in the Federal Register, and is not subject to comment," and asserting "FIFRA's registration process is indisputably more formal." Pet.14. But that FDA regulation was promulgated through notice-and-comment rulemaking, and here Monsanto never sought a label change that the agency could reject, nor has it provided "clear evidence" EPA would have rejected a cancer warning for Roundup notwithstanding the agency's (now-vacated) conclusion based on the record before it that glyphosate is "not likely" carcinogenic. As *Hardeman* explained, Monsanto's argument that EPA's re-registration of Roundup happened "in the context of a registration process that has the hallmarks of formal agency action" fails because § 136a(f)(2) provides that such registration is no defense to misbranding. 997 F.3d at 957 (cleaned up).

Similarly, the (now retracted) August 2019 Letter from a subordinate EPA official "did not follow any 'formal administrative procedure' that would give the letter the force of law." *Id.* Such informal assertions from a subordinate agency official are comparable to

interpretive rules or general statements of policy that "do not have the force and effect of law." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 97 (2015).[25] Nor does Monsanto point to any statutory authority giving a subordinate EPA official lone authority to accept or reject a label under FIFRA. *Cf. Merck*, 139 S. Ct. at 1683 (Thomas, J., concurring) ("complete response letters" issued under FDA's label-change regulation provide "no implication as to the ultimate approvability of the application") (emphasis omitted) (quoting 73 Fed. Reg. 39588 (July 10, 2008)).

In any event, the August 2019 Letter was retracted by a higher EPA official in the April 2022 Letter, and EPA's "not likely" conclusion

[25] "The absence of a notice-and-comment obligation makes the process of issuing interpretive rules comparatively easier for agencies than issuing legislative rules. But that convenience comes at a price: Interpretive rules do not have the force and effect of law and are not accorded that weight in the adjudicatory process." *Perez*, 575 U.S. at 97 (internal quotation marks omitted); *see also Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000) ("Interpretations such as those in opinion letters – like interpretations contained in policy statements, agency manuals, and enforcement guidelines . . . lack the force of law."); *United States v. Mead Corp.*, 533 U.S. 218, 234 (2001) ("interpretations contained in policy statements, agency manuals, and enforcement guidelines . . . are beyond the *Chevron* pale") (internal quotation marks omitted).

in the 2020 Interim Decision was vacated by the Ninth Circuit. Neither has any effect.

3. Monsanto's remaining express-preemption arguments lack merit

a. Monsanto unpersuasively invokes *Bates*, focusing on an example from that decision about a failure-to-warn claim requiring the word "DANGER" rather than "CAUTION." Pet.9. The example undermines Monsanto's arguments. EPA, by regulation, "establishe[d] four Toxicity Categories for acute hazards of pesticide products," 40 C.F.R. § 156.62, and then mandated toxicity warnings for qualifying pesticides, *id.* § 156.64. So when a state-law failure-to-warn claim requires "DANGER" when EPA's regulation requires "CAUTION," of course there is preemption: That is a "requirement[] for labeling" that is "different from" what EPA's regulation would "require[]." § 136v(b). There is no such regulation governing warning language for Roundup labels. If EPA believes as a policy matter that failure-to-warn claims involving glyphosate-based products should be barred, it can promulgate a regulation (subject to judicial review). It has not done so.

Monsanto's only countervailing point is that FIFRA's preemption provision seeks to promote uniformity, and the panel's decision could

permit States to reach different conclusions about particular warnings. Pet.15-16.

b. Last, Monsanto suggests that the panel's approach to FIFRA preemption will "reverberate" to other statutes that use similar express-preemption language. Pet.17. This argument is incorrect because what matters is not the "in addition to or different from" language, but the statutory schemes on which that language piggybacks.

For example, Monsanto refers to the Federal Meat Inspection Act. *Id.* That Act "establishes an elaborate system of inspecting live animals and carcasses," and "[o]ver the years, the [Department of Agriculture's Food Safety and Inspection Service] has issued extensive regulations" fleshing out that system. *National Meat Ass'n v. Harris*, 565 U.S. 452, 455-56 (2012) (cleaned up). Because that Act and its accompanying regulations impose many requirements, its preemption provision necessarily "sweeps widely" when blocking applications of additional or different state requirements. *Id.* at 459-60. Here, by contrast, EPA has promulgated "relatively few regulations," so FIFRA's preemption provision is "narrow." *Bates*, 544 U.S. at 452, 453 n.28.

E. Monsanto's 49-Year History Of Failing To Test Whether Long-Term Use Of Roundup Causes Cancer Further Counsels Against Preemption

1. Monsanto's position would have substantial negative effects. It would appear to bar all failure-to-warn claims based on a pesticide's "labeling" other than claims about the pesticide's efficacy. *See* Pet.12 n.3. But as *Bates* observed, "it seems unlikely that Congress considered a relatively obscure provision like § 136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability." 544 U.S. at 450.

That immunity also would hinder the functioning of FIFRA: state-tort actions "may aid in the exposure of new dangers associated with pesticides," giving manufacturers "added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement." *Id.* at 451 (internal quotation marks omitted). Just so with Carson, who used Roundup products on his lawn for thirty years. His extended exposure, and that of thousands of others, can help inform EPA about the long-term effects of glyphosate-based products like

Roundup and aid the agency in carrying out "its task of assessing the environmental and health dangers posed by pesticides." *Id.* at 440.

2. Monsanto's only policy point is that FIFRA's preemption provision seeks to promote uniformity, and finding no preemption could permit States to reach different conclusions about particular warnings. But the company again overlooks *Bates*, which cautioned against "overstat[ing] the degree of uniformity and centralization that characterizes FIFRA," observing "the statute authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Id.* at 450.

3. Monsanto's bid for preemption rests on its assertion that Roundup is not likely to cause cancer. But Monsanto never has tested Roundup properly to assess whether that is true. To the contrary, since Roundup was approved 49 years ago in 1974, Monsanto has worked steadily to avoid such testing and to hide or slant evidence that Roundup may in fact cause cancer, particularly for long-term users who were never told of the risks of such use or advised by Monsanto to wear protective gear or limit use. *See supra* pp.7-15.

Rather than test Roundup for long-term risks of cancer or provide such basic warnings, Monsanto instead has waged a nearly half-century campaign to pad its bottom line by using TV commercials that show people "spraying Roundup in shorts and without gloves," *Pilliod v. Monsanto Co.*, 282 Cal. Rptr. 3d 679, 692 (Cal. Ct. App. 2021), or that tell audiences they can "feel good" about using Roundup around kids and pets, App.20 (¶ 31). At the same time, the company seeks to avoid financial responsibility for the significant harms to human health that its product caused and that basic warnings might avoid. But the health and lives of ordinary citizens who used Roundup for long periods with no proper warnings should not be used as human currency to subsidize Monsanto's conduct.

Although Dr. Parry found evidence of genotoxicity and recommended further testing, "Monsanto did not conduct those studies and did not submit the expert's report to the EPA." *Chapman v. Monsanto Co.*, 2022 WL 3971287, at *10 (S.D. Tex.). Instead, Monsanto sought a different expert, Dr. Williams, to support its position on glyphosate and "ghostwrote an article under [his] name" – an article on which EPA relied in glyphosate papers. *Id.* at *9-10.

Further, at least three Monsanto toxicologists have suggested Roundup as formulated might cause cancer though they were reluctant to find out for certain: (1) Martens wrote that "if somebody came to me and said they wanted to test Roundup I . . . would react . . . with serious concern"; (2) Heydens wrote that "Glyphosate is OK but the formulated product (and thus the surfactant) does the damage"; (3) Farmer wrote that "you cannot say that Roundup is not a carcinogen because we have not done the necessary testing on the formulation to make that statement." *Hardeman*, 997 F.3d at 971 (quoting emails; alterations omitted). Based on such evidence, at least three juries (*Johnson*,[26] *Hardeman*,[27] and *Pilliod*[28]) now have assessed punitive damages against Monsanto for its callous conduct, and in each case the appellate court found the evidence sufficient to support such an award.

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[26] Jury awarded $250 million in punitive damages, reduced to just over $10 million. *Johnson v. Monsanto Co.*, 266 Cal. Rptr. 3d 111, 120, 129, 136 (Cal. Ct. App. 2020).

[27] Jury awarded $75 million in punitive damages, reduced to $20 million. *Hardeman*, 997 F.3d at 970.

[28] Jury awarded $2 billion in punitive damages to two plaintiffs, reduced to approximately $70 million. *Pilliod*, 282 Cal. Rptr. 3d at 697-98, 720.

Consistent with that don't-ask-don't-tell approach, Monsanto has admitted that it "has never conducted an epidemiological study to study the association between glyphosate-containing formulations and [cancer]"; "has not conducted a long-term animal carcinogenicity study on glyphosate since 1991"; and "has never conducted a 12-month or longer term animal carcinogenicity study on any surfactants used in glyphosate-based products." *Chapman*, 2022 WL 3971287, at *16 (quoting Monsanto's interrogatory responses). But such ostrich-like behavior is the antithesis of scientific transparency that would support Monsanto's claim (and EPA's now-vacated conclusion) that Roundup or glyphosate is "not likely" carcinogenic – particularly for longer-term use, which Monsanto admits never has been tested. *Cf. Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 191 (2015) ("the expression of an opinion may carry with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, *but that he does know facts which justify it*") (emphasis added) (quoting W. Page Keeton et al., *Prosser and Keeton on Torts* § 109, at 760 (5th ed. 1984)).

Monsanto's practice of hiding the defects in Roundup shows why personal-injury suits "may aid in the exposure of new dangers associated with pesticides," as an adjunct to the agency's misbranding power. *Bates*, 544 U.S. at 451. Indeed, civil lawsuits – not EPA review – finally revealed Monsanto's efforts to avoid proper testing that could show the cancer risks from using Roundup, and the internal judgments of its own toxicologists that Roundup might cause cancer. *See supra* pp.7-15 (detailing this history).

Because EPA relies on manufacturer-submitted materials when registering products, having the civil justice system as a counterbalance serves Congress's purpose in FIFRA to make pesticides safer for consumers. Lawsuits like Carson's provide "remedies that enforce federal misbranding requirements," which as *Bates* explained "would seem to aid, rather than hinder, the functioning of FIFRA." *Id.* Further, "lay juries are in no sense anathema to FIFRA's scheme" because in a criminal prosecution they "necessarily pass on allegations of misbranding." *Id.* at 452 (citing § 136*l*(b)).

Monsanto's ongoing campaign to skew the science and avoid doing the studies recommended by its own scientists to determine the cancer

risk of prolonged Roundup use is well-documented, and was geared to increase sales by avoiding basic warnings to wear protective gear.

There is no express preemption under FIFRA.

II. Carson's Failure-To-Warn Claim Is Not Impliedly Preempted

It is unclear from Monsanto's petition whether it intends to argue implied preemption. The doctrine of implied preemption does not apply to labeling requirements under FIFRA. But even if the doctrine applied, it would not bar Carson's claim.

A. There Is No Implied Preemption Under FIFRA

The doctrine of implied preemption does not apply under FIFRA. Implied preemption arises, for example, when a statute contains no express-preemption provision, but it is nonetheless impossible to comply with both state-law mandates (such as a duty to warn of cancer risks) and federal-law requirements. FIFRA does have an express-preemption provision, yet it leaves a broad role for state regulation of pesticides. FIFRA therefore strikes a careful balance. Congress decided that FIFRA preempts state requirements only when they impose labeling or packaging requirements "in addition to or different from those required under [FIFRA]." § 136v(b). Congress also preserved a state's authority

"to regulate the sale and use of pesticides" and "to ban the sale of a pesticide that it finds unsafe." *Pilliod*, 282 Cal. Rptr. 3d at 701. Those decisions left no room for claims of implied conflict.

Unsurprisingly, then, the Court in *Bates* did not conduct an implied-preemption analysis. The defendant had made the argument, *see* Brief for the Respondent 36-37, *Bates v. Dow AgroSciences LLC*, No. 03-388 (U.S. Nov. 24, 2004), 2004 WL 2758217, and if the Court had found implied preemption it would have affirmed rather than remanded. But as Justice Thomas observed in his concurrence, that refusal even to evaluate implied preemption "comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption." 544 U.S. at 459 (Thomas, J., concurring in the judgment in part and dissenting in part).

B. Even If Implied Preemption Could Apply To A State-Labeling Requirement Under FIFRA, It Does Not Apply To Carson's Failure-To-Warn Claim

Monsanto has drawn its implied-preemption arguments from drug cases under the Federal Food, Drug, and Cosmetic Act, such as *Merck* as discussed above in Part I.D.2.d. But courts conduct an implied-preemption analysis in those cases because Congress has "declined to

enact [an express-preemption] provision for prescription drugs." *Wyeth*, 555 U.S. at 567. Those cases have little relevance here because FIFRA has an express-preemption provision on the subject of labeling. But even setting that threshold issue aside, Monsanto's implied-preemption arguments lack merit.

Monsanto's theory to the panel was that it could not add a warning to Roundup's labels without EPA's approval, making it "impossible for a private party to comply with both state and federal requirements." *Merck*, 139 S. Ct. at 1672; Doc.49 at 45. For the same reasons discussed above under express preemption, EPA's registration of Roundup based on its "not likely" conclusion and the August 2019 Letter lacked the force of law to preempt. Those conclusions are even more powerful now that the Ninth Circuit has vacated EPA's conclusion and the August 2019 Letter was retracted.

For impossibility preemption to apply, a manufacturer must present "clear evidence" that the "drug manufacturer fully informed the [agency] of the justifications for the warning required by state law and that the [agency], in turn, informed the drug manufacturer that the [agency] would not approve a change to the drug's label to include that

warning." *Merck*, 139 S. Ct. at 1672. None of those factors is met here, and the mere "possibility of impossibility is not enough." *Id.* at 1678 (alteration omitted).

There is no "clear evidence" EPA would reject a cancer warning on Roundup labels, as *Merck* requires. EPA has promulgated no regulation requiring certain warnings on glyphosate-based product labels and barring others. Nor has the agency taken other formal action rejecting a warning about the cancer risks of Roundup. Instead, an agency official has said that if a company like Monsanto asked to include a warning that IARC "classified glyphosate as probably carcinogenic to humans," "this revised language could be approved by EPA." April 2022 Letter (App.119-20). That is the opposite of "clear evidence" showing Carson's claims are preempted, and *Merck* rejects Monsanto's speculative approach.

Nor did Monsanto ever fully inform EPA of the justifications for a cancer warning on Roundup. Rather, for 49 years since initial registration in 1974, Monsanto has waged a campaign to slant the science and declined to test Roundup as formulated to see whether long-term use causes cancer. *See supra* pp.7-15.

Implied impossibility preemption therefore also fails.

CONCLUSION

The Court should reverse the judgment of the district court and hold, consistent with this Court's panel decision, that Carson's state-law failure-to-warn claim is not preempted by FIFRA.

Dated: February 13, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limits of Federal Rule of Appellate Procedure 32(a)(7) because, according to the word-processing system used to prepare it (Microsoft Word 2016), it contains 11,655 words, excluding the portions of the brief exempted by Federal Rule of Appellate Procedure 32(f).

I further certify that this brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (a)(6) because it has been prepared using Microsoft Word 2016 in a proportionally spaced typeface (Century Schoolbook, 14 point).

/s/ David C. Frederick
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CERTIFICATE OF SERVICE

I hereby certify that on February 13, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ David C. Frederick
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ADDENDUM

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7 U.S.C. § 136. Definitions

For purposes of this subchapter—

* * *

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary

individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable

variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter—

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

* * *

(bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

7 U.S.C. § 136a. Registration of pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

* * *

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the

public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

* * *

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

* * *

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

* * *

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of—

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

* * *

7 U.S.C. § 136a-1. Reregistration of registered pesticides

* * *

(b) Reregistration phases

Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

* * *

7 U.S.C. § 136d. Administrative review; suspension

(a) Existing stocks and information

* * *

(2) Information

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

(b) Cancellation and change in classification

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—

(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and

analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection and section 136w(d) of this title, in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 136w(d) of this title and proceed in accordance with subsection (c) of this section. When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into

account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact

7 U.S.C. § 136j. Unlawful acts

(a) In general

(1) Except as provided by subsection (b) of this section, it shall be unlawful for any person in any State to distribute or sell to any person—

(A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

* * *

7 U.S.C. § 136*l*. Penalties

(a) Civil penalties

(1) In general

Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.

(2) Private applicator

Any private applicator or other person not included in paragraph (1) who violates any provision of this subchapter subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense, except that any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or uses dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than $500 for the first offense nor more than $1,000 for each subsequent offense.

(3) Hearing

No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged.

(4) Determination of penalty

In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever

the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

(5) References to Attorney General

In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court.

(b) Criminal penalties

(1) In general

(A) Any registrant, applicant for a registration, or producer who knowingly violates any provision of this subchapter shall be fined not more than $50,000 or imprisoned for not more than 1 year, or both.

(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, who knowingly violates any provision of this subchapter shall be fined not more than $25,000 or imprisoned for not more than 1 year, or both.

(2) Private applicator

Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this subchapter shall be guilty of a misdemeanor and shall on conviction be fined not more than $1,000, or imprisoned for not more than 30 days, or both.

(3) Disclosure of information

Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 136a of this title, shall be fined not more than

$10,000, or imprisoned for not more than three years, or both.

(4) Acts of officers, agents, etc.

When construing and enforcing the provisions of this subchapter, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.

7 U.S.C. § 136v. Authority of States

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

(c) Additional uses

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State.

(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.

(3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal

Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] that permits the residues of the pesticides on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 136w of this title, that a State is not capable of exercising adequate controls to assure that State registration under this section will be in accord with the purposes of this subchapter or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.

40 C.F.R. § 155.56
Interim registration review decision.

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in § 155.58 when issuing an interim registration review decision

40 C.F.R. § 155.58
Procedures for issuing a decision on a registration review case.

(a) The Agency will publish a notice in the Federal Register announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place in the pesticide's registration review docket the Agency's proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things:

(1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.

(2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.

(3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.

(4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

(c) After considering any comments on the proposed decision, the Agency will issue a registration review decision or interim registration review decision. This decision will include an explanation of any changes to the proposed decision and the Agency's response to significant comments. The Agency will publish a notice in the Federal Register announcing the availability of a registration review decision or interim registration review decision. The registration review case docket will remain open until all actions required in the final decision on the

registration review case have been completed.

(d) If the registrant fails to take the action required in a registration review decision or interim registration review decision, the Agency may take appropriate action under FIFRA.

40 C.F.R. § 156.10
Labeling requirements.

(a) *General—Contents of the label.* Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

* * *

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A)

of the Act, a pesticide or a device declared subject to the Act pursuant to §152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

* * *

(i) *Directions for Use*—(1) *General requirements*—(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain

effective results without causing unreasonable adverse effects on the environment.

(viii) Worker protection statements meeting the requirements of subpart K of this part.

(ix) Specific directions concerning the storage, residue removal and disposal of the pesticide and its container, in accordance with subpart H of this part. These instructions must be grouped and appear under the heading, "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See table in §156.60(b))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) For total release foggers as defined in §156.78(d)(1), the following statements must be included in the "Directions for Use."

* * *

(j) *Statement of use classification.* Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

40 C.F.R. § 156.60
General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) *Location of statements*—(1) Front panel statements. The signal word, child hazard warning, and, in certain cases, the first aid statement are required to appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) Statements elsewhere on label. Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) *Placement and prominence*—(1) Front panel statements. All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

* * *

40 C.F.R. § 156.62
Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In addition, toxicity categories may be used for regulatory purposes other than labeling, such as classification for restricted use and requirements for child-resistant packaging. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table in this paragraph.

ACUTE TOXICITY CATEGORIES FOR PESTICIDE PRODUCTS

Hazard Indicators	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	>50 thru 500 mg/kg	>500 thru 5,000 mg/kg	>5,000 mg/kg
Dermal LD_{50}	Up to and including 200 mg/kg	>200 thru 2000 mg/kg	>2000 thru 20,000 mg/kg	>20,000 mg/kg
Inhalation LC_{50}	Up to and including 0.2 mg/liter	>0.2 thru 2 mg/liter	>2 thru 20 mg/liter	>20 mg/liter
Eye irritation	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin irritation	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

40 C.F.R. § 156.64
Signal word.

(a) *Requirement.* Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in § 156.62. The signal word must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) *Toxicity Category I.* Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word "DANGER." In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word "Poison" must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word "Poison."

(2) *Toxicity Category II.* Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word "WARNING."

(3) *Toxicity Category III.* Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word "CAUTION."

(4) *Toxicity Category IV.* A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be "CAUTION."

(b) *Use of signal words.* In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

40 C.F.R. § 156.80
General.

(a) *Requirement.* Each product is required to bear hazard and precautionary statements for environmental hazards, including hazards to non-target organisms, as prescribed in this subpart. Hazard statements describe the type of hazard that may be present, while precautionary statements direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(b) *Location of statements.* Environmental hazard and precautionary statements may appear on any panel of the label and may be required also in supplemental labeling. The environmental hazard statements must appear together under the heading "Environmental Hazards." Typically the statements are grouped as a sub-category within the "Precautionary Statements" section of the labeling.

(c) *Type size.* All environmental hazard and precautionary statements must be at least 6 point type.

40 C.F.R. § 159.158
What information must be submitted.

(a) *General.* Information which is reportable under this part must be submitted if the registrant possesses or receives the information, and the information is relevant to the assessment of the risks or benefits of one or more specific pesticide registrations currently or formerly held by the registrant. Information relevant to the assessment of the risks or benefits also includes conclusion(s) or opinion(s) rendered by a person who meets any of the following

(1) Who was employed or retained (directly or indirectly) by the registrant, and was likely to receive such information.

(2) From whom the registrant requested the opinion(s) or conclusion(s) in question.

(3) Who is a qualified expert as described in § 159.153(b).

(b) *Exceptions*—(1) *Clearly erroneous information.* Information need not be submitted if before that date on which the registrant must submit such information if all of the following conditions are met:

(i) The registrant discovers that any analysis, conclusion, or opinion was predicated on data that were erroneously generated, recorded, or transmitted, or on computational errors.

(ii) Every author of each such analysis, conclusion, or opinion, or as many authors as can be contacted through the use of reasonable diligence, has acknowledged in writing that the analysis, conclusion, or opinion was improper and has either corrected the original analysis, conclusion, or opinion accordingly, or provided an explanation as to why it cannot be corrected.

(iii) As a result of the correction, the information is no longer required to be reported under FIFRA section 6(a)(2), or if no correction was possible, the authors agree that the original analysis, conclusion or opinion has no scientific validity.

(2) *Previously submitted information.* Information regarding an incident, study, or other occurrence need not be submitted if before the date on which the registrant must submit such information, the registrant is aware that the reportable information concerning that incident, study, or other occurrence is contained completely in one of the following:

(i) Documents officially logged in by the EPA Office of Pesticide Programs.

(ii) EPA publications, EPA hearing records, or publications cited in EPA FEDERAL REGISTER notices.

(iii) Any other documents which are contained in the official files and records of the EPA Office of Pesticide Programs.

(iv) Any documents officially logged in by the EPA Office of Pollution Prevention and Toxics under the provisions of section 8(e) of the Toxic Substances Control Act, provided that if the information pertains to a chemical compound which, subsequent to the submission of data under section 8(e), becomes the subject of an application for registration as a pesticide active ingredient, information is submitted to the Office of Pesticide Programs as required by 40 CFR 152.50(f)(3).

(3) *Publications.* A published article or report containing information otherwise reportable under this part need not be submitted if it fits into either of the following categories:

(i) Any scientific article or publication which has been abstracted in a recognized database of scientific and medical literature, such as Medline, ENBASE, Toxline or Index Medicus, if the abstract in question clearly identified the active ingredient or the registered pesticide(s) to which the information pertains. Otherwise reportable information received by or known to the registrant prior to publication of an abstract concerning the information must be reported and may not be withheld pending such publication.

(ii) Reports or publications which have been made available to the public by any of the following Federal agencies: Centers for Disease Control and Prevention, Consumer Products Safety Commission,

Department of Agriculture, Department of the Interior, Food and Drug Administration or any other agency or institute affiliated with the Department of Health and Human Services. Otherwise reportable information concerning research which was performed, sponsored, or funded by the registrant which may also appear in forthcoming Government reports or publications must be reported and may not be withheld pending publication.

(4) *Information concerning former inerts, contaminants or impurities.* Notwithstanding any other provisions of this part, a registrant need not report information concerning a chemical compound that was at one time an inert ingredient or a contaminant or impurity of a pesticide product, and would otherwise be reportable under this part, if both of the following conditions are met:

(i) The compound has been eliminated from its registered product due to changes in manufacturing processes, product formulation or by other means.

(ii) The registrant has informed the appropriate product manager in the Office of Pesticide Programs in writing of the presence previously of the inert, contaminant or impurity in the product and its subsequent elimination from the product.